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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M3369n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-10

December 23, 1999

Mr. George Makris
President
Fantis Foods, Inc.
60 Triangle Blvd.
Carlstadt, NJ 07072

Dear Mr. Makris:

During an inspection conducted on September 8, 1999 by the New Jersey Department of Health and Senior Services under contract with the Food and Drug Administration (FDA), at your firm located at 60 Triangle Blvd., Carlstadt, NJ 07027, violations of Title 21, Code of Federal Regulations, Part 123, (21 CFR 123) were documented. The violations of the Fish and Fishery Product regulations cause you [redacted] and [redacted] to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that your products were prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health.

The inspectional observation of concern is:

- The failure to develop and implement a written seafood HACCP plan for the control of pathogen growth and histamine formation during receiving and storage of whole double [redacted] and [redacted] in accordance with 21 CFR 123.6(b).

This observation was previously reported to you in a letter from this office dated [redacted] referencing an inspection by the New Jersey Department of Health performed under contract with the FDA.

The above item is not intended to be an all-inclusive list of violations. As an importer of seafood, you are responsible for assuring that your overall operation and the food products you produce or distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Jill Mielziner, Acting Compliance Officer, at the address and telephone number above.

Sincerely yours,

Roy Abrahams for

Douglas I. Ellsworth
District Director